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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/312,485	05/17/1999	PATRICE DEBREGEAS	065691/0163	2681

7590 09/08/2004  
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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/312,485

Applicant(s)

DEBREGEAS ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/11/04, 7/10/03.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Amendment filed on May 11, 2004 has been entered. Claims 11-20 are pending. In response to the election of species requirement set forth on September 22, 2003, on October 9, 2003 Applicant elected the species of Mannitol, as the neutral core substance, and *Gingko biloba*, as the plant substance.

Examiner has declared claims 11-20 to be allowable to the extent that they read on the species wherein the neutral core is of Mannitol and *Gingko biloba* is the plant substance. Accordingly, if the claims are amended to embrace such scope limited to the elected species, the claims would be allowed.

Any rejection that is not addressed in this Office Action is considered obviated in view of the amendment.

#### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-13, 15-17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Franz et al US Patent 4,411,882 ("Franz").

Applicant's arguments with respect to this rejection have been fully considered but are not persuasive. Applicant argues that Ergot alkaloids taught by Franz is not a plant substance, rather a fungus.

In response Examiner states the broadest reasonable interpretation of the limitation "plant substance" does not exclude Ergot alkaloids because it does not limit such substances to any specific plants. Plant substances as describe in page 6, para

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0021 of the specification are any substance that may be derived from plants. Ergot Alkaloids fall within the scope of such limitation, because it is isolated from a *Clavicep purpurea* that grows on rye and wheat and thus is derived from a plant. Therefore, Ergot alkaloids are within the scope of such limitation.

Further, Examiner adds that the term fungus, as described by Webster's II, New Riverside University Dictionary, is describe as any of numerous plants of the division or subkingdom Thallophyta. See Webster II at p. 512. Since *Clavicep Purpurea* is a fungus within the meaning of Webster's II, it is thus fall within the kingdom of plant. Therefore, alkaloid ergots are viewed to be within the scope of the instant limitation of "plant substance."

With respect to Applicant's arguments about the scope of the term neutral core, Examiner states that the granules of Franz meet such limitation. The recitation "neutral core" has been given its broadest reasonable interpretation consistent with the specification. Since the instant specification does not exclude the granules of Franz, such granules meet this limitation. "Neutral" is viewed to mean free of charge and "core" is viewed to mean the innermost layer. see definitions on Webster II, Riverside Dictionary. Thus, the recitation of "neutral core," is viewed to be an innermost layer that is free of charge. The pellets of Franz meet such limitations because they are free of charge and have a diameter size between he ranges of 0.5-1.25 mm in diameter which is well within the instantly claimed ranges of particle size. see col 1, lines 61-66.. Accordingly, Franz meets all elements of the instant claims and the rejection is maintained.

***Claim Rejections - 35 USC § 103***

Claims 11-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Franz.

Applicant's arguments with respect to this rejection have been fully considered but are not persuasive.

Applicant argues that Franz does not teach neutral core. (see Response at page 8). In rebuttal, Examiner replies that as argued above, the pellets of Franz meets the limitations of the instant "neutral core."

Applicant further argues that the instant claims does not intend to prepare prolong release formulation (see Response at page 8). Applicant's arguments are not commensurate with the scope of the claims. The scope of the instant claims does not exclude the coating process described by Franz. Franz teaches all method steps of the instant claims. Accordingly, it renders the claims obvious for the reasons of record.

Further, Applicant has not shown any evidence of criticality for rebutting the argument of record directed to optimization of the concentration of alcohol within the fluid mixture and the weight ratios of the coating per mass of the pellets in the process of Franz. Thus, the claims stand rejected.

***Conclusion***


**No claims are allowed. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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